

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL-PORTELA & CA. S.A.,)
BIAL-HOLDING, S.A. and)
SUNOVION PHARMACEUTICALS)
INC.,)
Plaintiffs,)
v.)) Civ. No. 18-304-CFC-CJB
ALKEM LABORATORIES)
LIMITED,)
Defendant.)

BIAL-PORTELA & CA. S.A.,)
BIAL-HOLDING, S.A. and)
SUNOVION PHARMACEUTICALS)
INC.,)
Plaintiffs,)
v.)) Civ. No. 20-786-CFC-CJB
ALKEM LABORATORIES)
LIMITED,)
Defendant.)

BIAL-PORTELA & CA. S.A.,)
BIAL-HOLDING, S.A. and)
SUNOVION PHARMACEUTICALS)
INC.,)
)
Plaintiffs,)
)
v.) Civ. No. 21-186-CFC
)
ALKEM LABORATORIES)
LIMITED,)
)
Defendant.)

MEMORANDUM ORDER

I held a bench trial in this consolidated ANDA case in June 2022. I set forth my findings of fact and conclusions of law in an opinion issued on September 15, 2022, D.I. 271, and directed the parties to submit a proposed order by which I could enter final judgment consistent with that opinion, D.I. 272. The parties submitted competing proposed judgments on September 30. D.I. 274. The proposals differ with respect to the disposition of Counts I through V of the Complaint filed by Plaintiffs (Bial) in C.A. No. 18-304-CFC-CJB (D.I. 1) and corresponding counterclaims filed by Defendant Alkem (D.I. 13). The five counts alleged infringement of patents that were not adjudicated at trial. Bial argues that I should dismiss the five counts and corresponding counterclaims as moot and without prejudice. D.I. 274 at 1–2. Alkem argues that these claims should be

dismissed with prejudice. D.I. 274 at 2. I will sign Alkem's proposed judgment for the following reasons.

In advance of the trial, I held a status conference call on May 4, 2022. At the outset of the call, in response to my request for an update on the case, Bial stated:

[T]he case has narrowed substantially There had been eight defendants and 11 patents. We now have two defendants and have substantially narrowed the claims to 15 per defendant, eight patents. We hope further narrowing may be possible for the issues at trial. The parties are continuing to work on that. There is the final pretrial order due to the Court tomorrow, May 5th, and we hope that beyond that, additional narrowing may be possible for the pretrial conference, in terms of the issues presented to the Court to decide.

D.I. 246 at 5:25–6:12. I responded that trying 15 claims in a single trial was “not realistic,” D.I. 246 at 6:22–23, and I asked if we should have two trials—one for each of the remaining defendants, D.I. 246 at 7:25–8:1. Bial’s counsel replied that Bial “had not considered that issue,” D.I. 246 at 8:14–15, that “there is potential overlap between cases,” D.I. 246 at 8:15–16, and that “we hope additional narrowing will be possible before trial,” D.I. 246 at 15:14–15.

In the proposed pretrial order filed on May 10—the May 5 deadline having been delayed at the parties’ request—Bial stated that it would assert at trial 15 claims across eight patents. D.I. 225 at 17–18.

On May 16, I docketed an oral order which reads in relevant part:

WHEREAS, the parties filed the proposed pretrial order (D.I. 225) on May 10, 2022; WHEREAS, the bench trial in this case is 24 days away, and, according to the pretrial order, Plaintiffs are still asserting 15 claims across eight patents (see D.I. 225 at 17-18); and WHEREAS, Plaintiffs' assertion of 15 claims across eight patents at this juncture makes clear that Plaintiffs have yet to focus adequately on the relative strength of their various infringement claims, the limited resources of this Court, the caseload of this Court, and the fact that the judge in this case, like any human being, has finite perceptive, retentive, and cognitive abilities; NOW
THEREFORE, . . . IT IS HEREBY ORDERED that if Plaintiffs do not narrow their case before noon on May 19, 2022 to four asserted claims, the Court will issue its trial opinion in due course as its caseload allows and will not entertain any application by Plaintiffs for injunctive relief before the Court issues its trial opinion.

May 16, 2022 Oral Order. In response to this order, Bial sent me a letter requesting permission to assert six claims at trial without losing the ability to seek injunctive relief. D.I. 230 at 1. I granted that request on May 19. Bial then confirmed that it would limit its trial presentation to six claims across five patents not asserted in Counts I through V of the Complaint.

In now asking me to dismiss as moot and without prejudice Counts I through V, Bial effectively seeks to amend its pleadings under Federal Rule of Civil Procedure 15. That rule confers on the court "extensive discretion to decide whether to grant leave to amend after the time for amendment as a matter of course has passed." *Bio-Rad Laby's, Inc. v. 10x Genomics, Inc.*, C.A. No. 15-152-RGA,

D.I. 561 at 3 (D. Del. July 9, 2019) (quoting Wright & Miller, *Federal Practice & Procedure Civil* 3d, § 1486 (2010)). Exercising my discretion, I will dismiss Bial’s withdrawn claims with prejudice.

In ANDA cases, plaintiffs routinely assert at the outset significantly more patent claims than they ever could realistically assert at trial. As trial approaches, plaintiffs reduce their asserted claims to a manageable number and defendants reduce their invalidity defenses. The finite resources of this Court and the parties make this narrowing process necessary. If I were to dismiss Bial’s withdrawn claims as moot and without prejudice, then Bial (and any future plaintiff) would receive a green light to engage in “essentially endless litigation,” *Bio-Rad*, D.I. 561 at 2, and this Court, with its overwhelming docket of patent cases, would grind to a halt.

It is also noteworthy here that when I raised the possibility of two trials, Bial never took a position and responded that “there is potential overlap between cases,” without further elaboration or requests. D.I. 246 at 8:14–17. In addition, in its response to my May 19 order, Bial simply asked that I allow it to assert two additional claims. D.I. 230. I granted that request, and Bial never raised any objections or expressed concerns that it would be prejudiced by withdrawing its other claims.

Accordingly, I will sign Alkem's proposed form of final judgment.

10-24-22

Date

Ch. F. Cull

CHIEF JUDGE